



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,618	03/01/2004	Antonius Franciscus van der Steen	2183-6375US	8842
72286 7590 11/18/2008 LEYDIG, VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 N. STETSON CHICAGO, IL 60601-6731				
EXAMINER				
SZMAL, BRIAN SCOTT				
ART UNIT		PAPER NUMBER		
3736				
MAIL DATE		DELIVERY MODE		
11/18/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/790,618

Applicant(s)

VAN DER STEEN ET AL.

Examiner

Brian Szmaj

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 6-8, 11, 13, 14, 18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) in view of Porat et al (2003/0220556 A1).

Torp et al disclose a means for real-time calculation and display of strain in ultrasound imaging and further disclose receiving signals from a tissue with a sensor for measuring the deformation of the tissue in a measuring plane defined by the sensor; a varying pressure exerted on the tissue; identifying strain of the tissue from the signals received by the sensor; relating the strain to at least one of either hardness or elasticity; correlating signals acquired consecutively over time, where the signals are representative of the deformation of the tissue at positions of the sensor moved with respect to other positions of the sensor; calculating by means of the correlating step, strain in a tissue surface or tissue volume part; displaying elasticity or hardness parameters of a tissue surface or tissue volume part; the signals are echographic data detected with an acoustic sensor; displaying elasticity or hardness parameters of the tissue with position information of the sensor or tissue; signals possessing an overlap are received; a processor for collecting and processing signals from the sensor to identify strain of the tissue and to relate strain to elasticity or hardness parameters of a

tissue surface or tissue volume part; a first activating means for activating data storage; and the activating means are connected with the correlation detection means to become active at a predetermined correlation. See Column 5, lines 11-34; Column 6, lines 14-17; Column 7, lines 54-61; and Column 8, lines 8-17.

Torp et al however fail to disclose moving the sensor along the tissue in a direction transverse to the measuring plane and while the tissue is subject to a varying pressure; the signals are received during practically continuous motion of the sensor; the signals come from a blood vessel wall and the data is received only during a specific time period; the sensor is movable through the blood vessel or body cavity for recording signals from tissue while being controllably moved along the tissue in a direction transverse to a measuring plane defined by the sensor; and the sensor is arranged in a catheter, which can be inserted into a blood vessel, the sensor recording signals under controlled pull back of the catheter.

Porat et al disclose a means for tissue characterization and further disclose moving the sensor along the tissue in a direction transverse to the measuring plane; the signals are received during practically continuous motion of the sensor; the signals come from a blood vessel wall and the data is received only during a specific time period; the sensor is movable through the blood vessel or body cavity for recording signals from tissue while being controllably moved along the tissue in a direction transverse to a measuring plane defined by the sensor; and the sensor is arranged in a catheter, which can be inserted into a blood vessel, the sensor recording signals under controlled pull back of the catheter. See Paragraphs 0286 and 0298.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Torp et al to include the ability to move the sensor along a blood vessel, as per the teachings of Porat et al, since it would provide a means of determining a tissue parameter along a length of tissue.

3. Claims 5, 10, 12, 15-17, 19, 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) in view of Porat et al (2003/0220556 A1) as applied to claims 1 and 13 above, and further in view of Panescu et al (5,848,969).

Torp et al and Porat et al, as discussed above, disclose a means for measuring a tissue parameter along a length of a blood vessel but fail to disclose the signals are optical data detected with an optical sensor; the signals at as assumed cyclic pressure change are received at predetermined time intervals in a pressure change cycle; the tissue is an artery moving during a heartbeat in the longitudinal direction, and the sensor is moved parallel to the longitudinal direction so that during at least one detection period the sensor has a fixed position relative to the wall of the artery; a position recording means coupled with the processor to record sensor positions; an actuator for controllably moving the sensor in the direction transverse to the measuring plane; the actuator has an adjustable speed of motion; a second activating means for activating the actuator; and the activating means can be connected with an ECG recording device to become active during a predetermined part of the heartbeat.

Panescu et al disclose a means for visualizing internal structures and further disclose the signals are optical data detected with an optical sensor; the signals at as assumed cyclic pressure change are received at predetermined time intervals in a

pressure change cycle; the tissue is an artery moving during a heartbeat in the longitudinal direction, and the sensor is moved parallel to the longitudinal direction so that during at least one detection period the sensor has a fixed position relative to the wall of the artery; a position recording means coupled with the processor to record sensor positions; an actuator for controllably moving the sensor in the direction transverse to the measuring plane; the actuator has an adjustable speed of motion; a second activating means for activating the actuator; and the activating means can be connected with an ECG recording device to become active during a predetermined part of the heartbeat. See Column 3, lines 59-67; Column 4, lines 1-5; Column 6, lines 61-65; Column 10, lines 44-67; Column 11, lines 1-12, 25-35 and 56-63; and Column 17, lines 21-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Torp et al and Porat et al to include the ability to control the movement of the sensors, as per the teachings of Panescu et al, since it would provide a means of accurately measuring a tissue parameter along a length of tissue.

Allowable Subject Matter

4. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. Applicant's arguments filed August 15, 2008 have been fully considered but they are not persuasive.

Regarding Claims 1 and 13, the Applicants argue Torp et al fail to disclose the claimed step of: "relating the strain to at least one of either the hardness or elasticity properties of the tissue"; and the apparatus limitation of an "apparatus for generating hardness information of tissue". The Applicants further argue Torp et al do not disclose a strain measurement, but instead teach the measurement of strain velocities, which is the measurement of the rate of change of the strain, and not what the Applicants disclose. The Examiner respectfully disagrees. In Column 1, lines 34-39 and 49-51, Torp et al discloses strain measurements are related to the hardness of tissue. Therefore, the measurement of strain in Torp et al is related to the measurement of the tissue hardness or elasticity. While Torp et al does disclose the use of strain velocities, the disclosure of Torp et al clearly teaches strain velocity is also known as the strain rate (see Column 2, lines 57-58). Furthermore, if strain velocity is the measurement of the rate of change in strain, one of ordinary skill in the art would recognize the fact that strain must be first measured in order to calculate a rate of change in strain. With regards to Claim 13, the Applicants also argue Torp et al does not disclose "a display device for displaying elasticity and/or hardness parameters of the tissue surface". The Examiner respectfully disagrees. As stated above, Torp et al does disclose the

determination of the hardness of the tissue, and also clearly discloses the use of a display in Figure 1.

Furthermore, regarding Claims 1 and 13, the Applicants argue Porat et al do not disclose the method step of: "the sensor is moved during the receiving step: (a) in a direction transverse to the measuring plane, and (b) while the tissue is subject to varying pressure". The Examiner respectfully disagrees. Porat et al discloses the use of an intravascular device that is used to determine types of arterial plaque. In order to characterize the type of plaque in a blood vessel, the catheter would inherently have a measurement means situated in a plane that is transverse to the longitudinal axis of not only the catheter, but the blood vessel as well, since the blood vessel wall is being measured. See Figure 2c and Paragraph 0286. Therefore, during movement of the catheter along the longitudinal axis of the blood vessel, the measurement means is acquiring data in a plane that is transverse to the longitudinal axis of the blood vessel and catheter. The Applicants also argue Porat et al fail to disclose "the tissue is subject to a varying pressure", which means the tissue is subject to a varying pressure as a result from a heartbeat. The Examiner respectfully disagrees. While Porat et al does not explicitly disclose blood vessel movement due to a heartbeat, one of ordinary skill in the art would recognize that Porat et al inherently discloses the varying pressure (due to a heartbeat), since arterial plaque measurements take place on a live patient, and therefore the tissue is subject to a varying pressure (from a heartbeat).

Regarding Claim 12, the Applicants argue Panescu et al fail to disclose "the tissue is an artery moving during the heartbeat in the longitudinal direction, and the

sensor is moved parallel to the longitudinal direction, so that, during at least one detection period, the sensor has a fixed position relative to the wall of the artery". In particular, the Applicants argue Panescu et al fail to teach the blood vessel moves while the sensor is receiving signals, and the device is not moved in a parallel direction to the tissue's direction of motion such that the sensor has a fixed position relative to the tissue. The Examiner respectfully disagrees. Panescu et al discloses the use of an imaging catheter that is used in the diagnosis and treatment of intravascular ailments in association with angioplasty or atherectomy techniques (see Column 4, lines 5-8). While Panescu et al does not explicitly disclose blood vessel pulsation, one of ordinary skill in the art would have known that blood vessels pulsate in response to the heart rhythm of the patient. Since Panescu et al discloses the device can be used in angioplasty techniques, one of ordinary skill in the art would be able to determine the patient is alive, and therefore has a heart rhythm, and therefore would have blood vessel pulsations that the device would experience while imaging the blood vessel. Furthermore, since Panescu et al discloses the device can be used in angioplasty techniques, one of ordinary skill in the art would since been able to recognize the device is moved in a parallel direction to the tissue's direction of motion.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736